SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET		
		Day	Month	Year				Day	Month	Year
PRIVACY	COSTA RICA		PRIVACY		47 Years	Female	65.00 kg	02	MAR	2025

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)

Two masses on the soles of the feet [Mass]
Stomach pain [Abdominal pain upper]
Colitis [Colitis]
Itchy eye [Eye pruritus]
Gas [Flatulence]
Foot discomfort [Limb discomfort]
Weight loss [Weight decreased]
Very tired [Fatigue]
Diarrhea, 6/10 bowel movements, #3 is the maximum in 24 hours [Diarrhoea]
White blood cell count was low at 3.3 [White blood cell count decreased] **(Continued on Additional Information Page)**

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION
- ☒ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1) Abemaciclib (Abemaciclib) Tablet {Lot # D763191; Exp.Dt. OCT-2026}

20. DID REACTION ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☒ NA

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 150 mg, bid	#1) Oral

17. INDICATION(S) FOR USE
#1) Breast cancer (Breast cancer)

21. DID REACTION REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☒ NA

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) 02-MAR-2025 / Ongoing	#1) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

#1) ARIMIDEX (ANASTROZOLE) Unknown ; Unknown
#2) VITAMIN C [ASCORBIC ACID] (VITAMIN C [ASCORBIC ACID]) Unknown ; Unknown
#3) CALCIUM (CALCIUM) Unknown ; Unknown
#4) VITAMIN D NOS (VITAMIN D NOS) Unknown ; Unknown
#5) GOSERELIN (GOSERELIN) Unknown ; Unknown
#6) ENALAPRIL (ENALAPRIL) Unknown ; Unknown

23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

From/To Dates	Type of History / Notes	Description
Unknown	Medical Condition	Insomnia (Insomnia)
Unknown	Medical Condition	Hot flashes (Hot flush)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
Eli Lilly Interamerica Inc (AR Branch)
Tronador 4890 - Piso 12
Buenos Aires, Capital Federal CP: 1430 ARGENTINA
Phone: 54 1145464000

26. REMARKS

24b. MFR CONTROL NO.
CR202503016367

24c. DATE RECEIVED BY MANUFACTURER
28-MAY-2025

24d. REPORT SOURCE
☒ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL ☐ OTHER:

DATE OF THIS REPORT
03-JUN-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 4

25b. NAME AND ADDRESS OF REPORTER
NAME AND ADDRESS WITHHELD.
NAME AND ADDRESS WITHHELD.
NAME AND ADDRESS WITHHELD.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Case Description: This solicited case, reported by a consumer via a patient support program (PSP) from a business partner, with additional information from the initial reporter via PSP, concerned a 47-year-old female patient of unknown ethnicity.

Medical history included high blood pressure, mass, nail growth abnormal, insomnia and hot flashes. Procedures included foot surgery for a toenail that developed on one foot and a mole on the sole of the other foot. Concomitant medications included vitamin C, calcium and vitamin D for unknown indications, and enalapril for high blood pressure.

The patient received abemaciclib (Verzenio) coated tablets, 150 mg, every 12 hours, orally, for the treatment of breast cancer, beginning on 02-Mar-2025. Concomitantly, she also received anastrozole (Arimidex) and goserelin, for an unknown indication. On 02-Mar-2025, while on abemaciclib therapy, she had diarrhea with 4 bowel movements. On 12-Mar-2025, while on abemaciclib therapy, she experienced diarrhea with 6/10 bowel movements, three was the maximum in 24 hours, and stomach pain. She had diarrhea for approximately 15 days after starting the treatment. She had one to three very loose bowel movements per day. On 13-Mar-2025, she had two diarrheal bowel movements. On 14-Mar-2025, she did not have diarrhea but had stomach pain. On 15-Mar-2025, she had two diarrheal bowel movements. On 16-Mar-2025, she had stomach pain and felt very tired. On 17-Mar-2025, she had colitis and gas. On 18-Mar-2025, she had one diarrheal bowel movement and at 1:00 pm she had colitis pain, for which she took one butylscopolamine bromide (Buscapina). On 19-Mar-2025, she did not have stomach pain or diarrhea. On an unknown date in Mar-2025, she had eye itching. She did not receive corrective treatment for diarrhea and abdominal pain upper. Since an unknown date, while on abemaciclib therapy, she experienced discomfort in the sole of her feet for several days. Approximately on 20-Mar-2025, she experienced two masses which prevented her from walking. This event was considered serious by the reporter due to disability reasons. A biopsy was performed on the right mass and on the other (no values, units or baseline were provided). Also, a small tumor was removed from the left side of the sole of her foot. As of 24-Mar-2025, she was feeling well, not in pain and no further treatment was indicated. On 04-Apr-2025, she underwent complete laboratory tests, which indicated that her white blood cell count was low at 3.3 and the reference was above 5 (unspecified unit). Subsequently, she continued diarrhea with 1 to 2 bowel movements per day for two and a half months. As a corrective treatment, she received loperamide. She also lost 2 kg in weight during the first month of treatment. She made lifestyle changes, eating healthy and going to the gym. Information regarding other corrective treatments was not provided. Outcome of the event diarrhea was resolved, weight loss was resolving while remaining events was not recovered. Status of abemaciclib therapy was ongoing.

The initial reporting consumer related the event diarrhea and weight loss while did not provide relatedness assessment of the events with abemaciclib therapy.

Update 26-Mar-2025: Additional information was received from the initial reporting consumer via a PSP on 19-Mar-2025. Added medical history (insomnia and hot flashes), concomitant medication (vitamin C, calcium, vitamin D, anastrozole (Arimidex) and goserelin), four non-serious events of (flatulence, colitis, eye pruritis and fatigue), added lot number (D763191) and expiry date (Oct-2026) of suspect drug abemaciclib therapy. Updated narrative and relevant fields.

Update 26-Mar-2025: Information received on 21-Mar-2025 and 24-Mar-2025 were processed together.

Update 27-Mar-2025: Additional information received on 24-Mar-2025 from the initial reporter via PSP. Added serious event of mass, a non-serious event of foot discomfort and a biopsy in laboratory tests. Updated narrative with new information.

Update 28-Apr-2025: Additional information received on 23-Apr-2025 from the initial reporter via PSP. Added blood pressure high, mass and nail growth abnormal as medical histories, foot surgery as a historical procedure, a lab data of white blood cell count, enalapril as a concomitant drug, and a non-serious event of white blood cell count decreased. Updated narrative with new information.

Update 16-May-2025: Additional information received on 12-May-2025. No changes were made to the case.

Update 03-Jun-2025: Additional information received on 28-May-2025 from the initial reporter via PSP. Added one non serious event of weight loss, lab data of weight loss, weight of patient, treatment drug loperamide. Updated outcome of diarrhea as resolved from resolving, causality of diarrhea as yes from no and narrative with new information.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	14-APR-2025	Weight decreased 2 kg weight loss		
2	14-APR-2025	White blood cell count Positive Low (unit, reference range, and values were not provided)	3.3	above 5

Mfr. Control Number: CR202503016367

ADDITIONAL INFORMATION

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown	Medical Condition	Blood pressure high (Hypertension);
Unknown to Ongoing	Medical Condition	Mass (Mass);
Unknown	Medical Condition	Nail growth abnormal (Nail growth abnormal);
Unknown	Procedure	Foot surgery (Foot operation);